CLAIMS

1. A process for the preparation of micronised particles of a glycopyrronium pharmaceutically acceptable salt, the process comprising the steps of:

feeding the micronisation chamber of a wet milling apparatus, optionally containing grinding media, with a water immiscible hydrocarbon or derivative thereof which is liquid at room temperature and pressure, also having a dielectric constant lower than 15 and a density of 1.3 to 2 g/cm^3 (the anti-solvent);

suspending the particles of the glycopyrronium salt in said anti-solvent,

micronising said suspended particles at a pressure equal to or lower than 200kPa;

optionally, drying the obtained micronized particles;

whereby at least 90% of said micronized particles have a diameter of less than 10 micron.

2. The process according to claim 1, further comprising the step of collecting the obtained micronized particles.

3. The process according to claim 1 or 2, wherein the pharmaceutically acceptable salt is organic or inorganic.

4. The process according to claim 3, wherein the inorganic salt is selected from the group consisting of fluoride, chloride, bromide, iodide, phosphate, nitrate and sulphate.

5. The process according to claim 4, wherein glycopyrronium is in form of the bromide salt.

6. The process according to claim 5, wherein glycopyrronium is in form of the racemic mixture of the enantiomers (3S,2'R), (3R,2'S).

7. The process according to any one of the preceding claims, wherein the anti-solvent is an n-alkane or ~~an~~ haloalkane which are liquid at room temperature and

pressure.

8. The process according claim 7, wherein the n-alkane anti-solvent is n-heptane.

9. The process according to claim 7, wherein the haloalkane anti-solvent is a fluoroalkane or a hydrofluoroalkane.

10. The process according claim 9, wherein the anti-solvent is selected from the group consisting of perfluorodecane, decafluoropentane and 2H,3H-decafluoropentane.

11. The process according to any preceding claim, further comprising a washing step in which a second anti-solvent is used to wash the micronised drug particles.

~~12. Physically stable micronised crystalline particles of a glycopyrronium pharmaceutically acceptable salt having a cohesive-adhesive balance (CAB) value of 0.5-1.5 obtainable by the process of any one claims 1 to 11.~~

~~13. A pressurized formulation for inhalation comprising the micronised particles of claim 12 suspended in a pressure-liquefied propellant.~~

~~14. A pressurized metered dose inhaler (pMDI) filled with the formulation of claim 13.~~

~~15. A dry powder formulation comprising the micronised particles of claim 12 in admixture with particles of a physiologically acceptable, pharmacologically inert solid carrier.~~

~~16. A dry powder inhaler filled with the formulation of claim 15.~~